

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-38, 81-92 in the reply filed on August 21, 2009 is acknowledged.
2. Applicant's addition of claims 93-97 is acknowledged and has been entered.
3. Applicant's cancellation of claims 3, 12, 14, 16, 20-21, 23-27, 29, 32-33, 38, 48, 60, 83-92 is acknowledged and has been entered.
4. Applicant's amendment of claims 1, 5, 17-19, 22, 30-31, 81 is acknowledged and has been entered.
5. Claims 1-2, 4-11, 13, 15, 17-19, 22, 28, 30-31, 34-37, 81-82, 93-97 are currently pending and under examination.
6. Claims 39-47, 49-65, 67-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 21, 2009..

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 22, 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to teach combining a fourth fluid and second fluid while transferring the first, third, and second fluids to a reaction site, or a sixth fluid formed from mixing a fourth and fifth fluid. In fact, there is no mention of a fifth or sixth fluid at all, and the presence of the fourth fluid was originally mixed with a third fluid for forming the second fluid (see original claim 22).

9. Claim 97 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification does not appear to disclose the limitation of introducing a sample from a vessel different from the vessel containing the first, third, and second fluids. While the specification discloses that the sample may be placed downstream of the reagent fluids within the same vessel, or applied directly to the reaction site (p. 22, 23), there is no indication that the sample is placed in a different vessel.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 2, 4, 6-11, 13, 16-19, 34-37, 81-82, 93, 96, 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Sia et al. [US 2007/0298433].

With respect to claims 1, 81, 82, Sia et al. teach a vessel containing two or more distinct assay fluids separated by a third fluid that can be immiscible with both and stored for greater than a day, and wherein the fluids may be transferred from the vessel to a reaction site in series without contact between any of the assay fluids (para. 0068-72).

12. With respect to claims 2, 4, 93, the vessel may be connected to a device comprising the reaction site on a common platform, such as in a microfluidic device (para. 0030, 0068).

13. With respect to claim 6, the vessel may be a tube (para. 0070).

14. With respect to claims 7-9, Sia et al. teach applying a pressure differential such as a vacuum downstream of the reaction site or pumps, which would be upstream of the reaction site (para. 0070-0071).

15. With respect to claims 10, 11, Sia et al. teach delivery of the fluids with actuation of any device that controls the rate, the order, or timing of introduction of either the first or second fluids to the reaction site (para. 0068).

16. With respect to claim 13, Sia et al. teach a microfluidic device (para. 0030, 0068).

17. With respect to claim 16, Sia et al. teach antibodies associated with the reaction site (para. 0049, 0072).

18. With respect to claims 17, 18, Sia et al. teach that the second solution is a rinse solution separated from the first solution by an air plug (para. 0068).

19. With respect to claims 19, 96, Sia et al. teach flowing a sample prior to flowing the solutions over the surface (para. 0011).

20. With respect to claim 34, Sia et al. teach fluids comprising gold-conjugated antibodies (para. 0049).

21. With respect to claims 35-36, the fluids comprise metal precursors that are electrolessly deposited on the reaction site (claims 74, 79-82).

22. With respect to claim 37, Sia et al. teach determining light transmittance (claim 48).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sia et al. [US 2007/0298433].

With respect to claims 28, 30-31, Sia et al. discloses an embodiment where all the components, which would include the vessel, are microfluidic, with cross-sectional diameters of less than 1mm, or 500 microns and ratio of length to cross-section of 10:1 (para. 0039-0041). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious for the vessel of Sia et al., which may be a tube, to have cross-sectional diameters of less than 1mm, or 500 microns and a ratio of length to cross-section of 10:1, through normal optimization procedures known in the art.

25. Claims 5, 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sia et al. [US 2007/0298433] in view of Jeon et al. [US 6,705,357].

With respect to claims 5, 94, Sia et al. teach the invention as discussed above, but fail to explicitly teach that the vessel is integrally connected to the reaction site, and that the vessel comprises at least a first and second branch in fluid communication.

Jeon et al., however, teach a vessel integrally connected to a reaction site comprising first and second branches in fluid communication (fig. 1). Jeon et al. further teach that this system allows for combining and distributing fluids, and for producing gradients in the fluids on a small scale, which is useful for studying biological phenomena that depend on concentration, such as in cell-surface interaction, high-throughput screening, biological pattern formation (column 4, line 50 - column 5, line 20).

Therefore, one of ordinary skill in the art at the time of the invention would have found it obvious to have utilized the vessel of Jeon et al. to deliver fluid to a reaction site, in order to enable the study of studying biological phenomena that depend on concentration, such as in cell-surface interaction, high-throughput screening, biological pattern formation.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 1, 2, 7, 8, 11, 13, 35-37, 81-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-46, 48, 51-53, 72-102 of copending Application No. 10/584,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application recite a method comprising flowing in series in the microfluidic channel a predetermined sequence of fluid plugs comprising a first and second fluids separated by a third immiscible fluid to a reaction site such as a binding region, and accumulating an opaque material, wherein the fluids are stored in a sealed vessel for over a month (claim 45, 96-98). Therefore, the conflicting claims encompass a narrower embodiment that would render the instant claims obvious.

The claims further recite that the fluids may be introduced by applying a vacuum (claim 99) and the fluids comprise metal precursors that are electrolessly deposited and light absorbence is detected (claims 46, 48, 74, 79-82).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

28. No claims are allowed.
29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Primary Examiner, Art Unit 1641